REMARKS

Applicants submit this paper in response to the final office action the Office mailed on December 8, 2005.

Amendments to the specification revise the cross-reference to priority applications and correct typographical errors and informalities in the specification.

New claims 80-94 and 106-118-recite treatment for humans and new claims 95-105 recite treatment for non-human primates. Support for the dosages recited in new claims 94, 117 and 118 is at least at paragraphs 599 and 628 of the specification. Support for the parenteral administration recited in new claims 93, 104 and 116 is at least at paragraphs 41, 271, 283 and 285 of the specification.

The amendments introduce no new matter.

Nonstatutory double patenting

The Office provisionally rejected claims 50-56, 58, 60-74 and 76-79 under judicially created obviousness-type double patenting over claims 1-4 and 9-11 of copending application No. 10/651,515. Applicants respectfully traverse the rejection. The judicially created law of obviousness-type double patenting was developed to cover the situation where patents or applications are not citable as a reference against each other and therefore can not be examined for compliance with the rule that only one patent is available per invention. Double patenting is thus applied when neither patent is prior art against the other, usually because they have a common priority date. *Eli Lilly and Co. v. Barr Laboratories Inc. et al.*, 251 F.3d 955, 58 U.S.P.Q. 2D 1865 (Fed. Cir. 2001). Application No. 10/651,515 has different priority dates from the present application and rejection under obviousness-type double patenting is inappropriate in this situation. In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection.

35 U.S.C. § 112, first paragraph

The Office rejected claims 50-56, 58, 60-74 and 76-79 as allegedly not enabled for preventing innate immune suppression due to radiation exposure. Applicants respectfully traverse the rejection.

Applicants traverse the Office's reasoning in alleging that "the skilled artisan would have to search the prior art to find, if possible, a model for determining a person prone to innate immune suppression as defined by the present specification and, thus, in need of preventive treatment." Evidence of record contradicts this allegation. For example, Applicant's own specification teaches that innate immune suppression can be associated with exposure of individuals to, e.g., radiation, chemotherapy, bone marrow transplantation or stem cell transplantation (see, e.g., paragraphs 229, 354 and 546-549). U.S. patent No. 5,461,042, discussed below under Section 103(a), also describes situations where immune suppression can reasonably be expected, e.g., exposure of individuals to radiation, chemotherapy or transplantation procedures (see, e.g., column 1, lines 14-23, column 4, lines 22-35 and column 18, lines 2-13).

In view of this, the rational basis for the Office's assertion is unknown to Applicants. Applicants therefore request under M.P.E.P. § 2144.03(C) the Examiner to cite references or knowledge the Examiner relies on to support the allegation at the paragraph bridging pages 3-4 of the office action. Applicants submit that this assertion is not properly officially noticed or based on common knowledge.

Applicants request reconsideration and withdrawal of the rejection.

35 U.S.C. § 103(a)

The Office rejected claims 50-56, 58, 60-74 and 76-79 as allegedly anticipated by U.S. patent No. 5,461,042 (hereafter '042). Applicants respectfully traverse the rejection to the extent it applies to the amended claims.

In the office action at 10 (pages 5 and 6), the Office asserted that the '042 patent disclosed that a 0.2-30 mg/day was a preferred dose range. Applicants traverse this characterization. At column 17, lines 40-41, the '042 patent states:

> "In larger adult mammals daily dosage of 0.2 to 30 mg/da. of AED is a preferred dosage. In larger adult mammals daily dosage of 0.2 to 30 mg/da. of AED is a preferred dosage. For AET the preferred dosage is usually in the range of 0.001 to 20 mg/da, with 0.001 to 1 mg/da. being the more preferred dosage. However, the dosage will vary depending on the route of administration. Subcutaneous, inhalation and intrathecal administration are methods that would require lower dosages of the active agents."

The stated preferred dose rage is thus specified as being for larger adult mammals. New independent claim 80 recites a dose range of 1-10 mg/kg/day for treating humans. When one considers this claim, it is clear that the dose range the '042 patent describes is significantly lower than what is presently claimed. Thus, for an adult human weighing 50 kg or 100 kg, the claimed doses for 3β,17β-dihydroxyandrost-5-ene would range from 50 mg at a dosage of 1 mg/kg for a 50 kg adult to 1,000 mg at a dosage of 10 mg/kg for a 100 kg adult. The 0.2 to 30 mg dose range for 3β,17β-dihydroxyandrost-5-ene the '042 patent describes is completely below this range. The same conclusion applies to new independent claim 95, which recites a dose range of about 4-40 mg/kg/day for non-human primates.

At item 11 of the office action, the Office asserted that the determination of dosages and/or treatment regimen is routine in the medical art and, thus, recitation of a known treatment in terms of dosages and/or treatment regimen is not patentable absent a showing of criticality. The Office cited *In re Russell*, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971) in support of this assertion.

Contrary to the Office's assertion, *Russell* did not discuss the issue of criticality and it had nothing to do with any medical treatment protocol. That case dealt with shampoo compositions that had unexpected properties compared to prior shampoos. To applicant's knowledge, there is no authority that states what the Office asserts here for medical treatment methods. The courts have warned against the use of *per se* rules in assessing obviousness, since each case must be decided on its own unique facts, e.g., *In re Ochiai*, 71 F.3d 1565; 37 U.S.P.Q.2D 1127 (Fed. Cir. 1995).

Applicants therefore request under M.P.E.P. § 2144.03(C) the Examiner to cite references or knowledge the Examiner relies on to support the allegation based on *In re Russell* at the paragraph at the bottom of page 6 of the office action. Applicants submit that this assertion is not properly officially noticed or based on common knowledge. The basis for this allegation is unknown.

The presently claimed subject matter recites dosages that are outside the teaching of the '042 patent cited above, which weakens the Office's assertion of obviousness. *In re Baird*, 16 F.3d 380 (Fed. Cir. 1994). The '042 patent contains no teaching that would lead one of ordinary skill in the art to increase dosages above what the patent expressly teaches at column 17, lines 40-41 for mammals larger than rodents. Drug developers usually look for the minimum effective dosage to minimize side effects or toxicities, so there is no motivation to increase dosages and there is no motivation to increase dosing from a single dose to multiple doses. In view of the foregoing, one of ordinary skill in the art had no reason to look for either (1) higher dosages or (2) dose regimens that differ from the single administration that the '042 patent showed to be effective. Since the '042 patent provides no motive to change its protocols or teaching, the Office has not presented a prima facie case of obviousness. *Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 192 F.3d 1353; 52 U.S.P.Q.2D 1294 (Fed. Cir. 1999); M.P.E.P. §§ 2143.01(I), (III) and (IV). Based on this record, the rejection is based on hindsight, which is impermissible. *In re Dembiczak*, 175 F.3d 994; 50 U.S.P.Q.2D 1614 (Fed. Cir. 1999).

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection.

Concluding remarks

Please charge any additional fees, except the issue fee, that are due now (except the issue fee), or credit any overpayment to Deposit Account No. 501536.

Respectfully submitted,

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By: Daryl D Muenchau

Daryl D. Muenchau, Reg. No. 36,616
Hollis-Eden Pharmaceuticals, Inc.
4435 Eastgate Mall, Suite 400
San Diego, CA 92121